

## **REMARKS**

Claim 10 has been canceled without prejudice or disclaimer. Claims 1-5, 7, 11-13, 16, 20 and 23-25 are amended. Support for the amended claims appears throughout the specification as filed and in the original claims. For example, support for amended claim 1 appears, e.g., at p. 4, line 15 to p. 5, line 31 and p. 6, lines 9-18. Support for amended claims 12-13 appears, e.g., in Example V. Claims 2-5, 7, 11-13, 16, 20 and 23-25 have also been amended to address various formalities.

The drawings have been amended to identify abbreviations and figure legends as requested by the Examiner. Support for the amendments appears, e.g., at p. 7, lines 12-20 and p. 38, line 5 to p. 42, line 29.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

### **I. Priority**

The Examiner states that the priority date granted for the instant invention is October 22, 2004, i.e., the filing date of PCT/DK04/00730. However, Applicants respectfully submit that the instant invention is fully supported by the Danish priority document DK 2003 01562, filed October 23, 2003, as well as United States provisional application 60/515,000 filed October 28, 2003, the priority or benefit of which are claimed by the instant application. Applicants respectfully request that the Examiner so acknowledge with the next Communication.

### **II. Drawings – Objections**

The Examiner has objected to the drawings for reciting abbreviations that are not defined therein and having figure legends which are allegedly not sufficiently descriptive. Applicants respectfully submit that the amended drawings submitted on Replacement Sheets pursuant to 37 C.F.R. 1.84 and 1.121 herewith overcome the Examiner's objections. Applicants respectfully request reconsideration and withdrawal of the objection.

### **III. Claims – Objections**

The Examiner has objected to the claims for various formal reasons. Applicants have amended the specification and identified claims as requested by the Examiner, thus obviating these objections.

**IV. The Rejection of Claims 1-5, 7 and 10-13 under 35 U.S.C. 101**

Claims 1-5, 7 and 10-13 stand rejected under 35 U.S.C. 101 as allegedly directed to non-statutory subject matter. Applicants have amended the claims to recite an "isolated" protease, thus obviating this rejection. Applicants respectfully request reconsideration and withdrawal of the rejection.

**V. The Rejection of Claims 1-5, 7, 10-13 and 24-25 under 35 U.S.C. 112 (Second Paragraph)**

Claims 1-5, 7, 10-13 and 24-25 stand rejected under 35 U.S.C. 112, second paragraph as allegedly being indefinite. This rejection is respectfully traversed.

The Examiner has alleges that the recitation of stringency conditions and the phrase "complementary strand" of claims 1 and 10 renders these claims indefinite. Solely to expedite prosecution, Applicants have amended claim 1 to delete reference to these terms, and have canceled claim 10, thus obviating this aspect of the rejections.

The Examiner alleges that claim 5 is unclear as to whether the phrase "comprising a substitution ... of one or more amino acid residues" modifies the parent protease or the variant protease. Applicants respectfully submit that the claim terminology is clear. The specification as filed clearly sets forth the protease modifications and variants according to the invention. See, e.g., p. 5, lines 7-20.

The Examiner also alleges that the phrase "trypsin like" in claim 11 renders the claim indefinite. Applicants respectfully submit that the claim terminology is clear. The specification as filed clearly sets forth the activity of a trypsin like protease. See, e.g., p. 4, lines 30-35.

The Examiner alleges that the recitation of the phrase "after storage at 35 °C" renders claims 12-13 unclear, and that the steps and reagents for determining residual activity are not disclosed. While Applicants disagree with the Examiner's assertion, the amended claims recite the duration of time for storage as requested by the Examiner. Moreover, Example V as filed clearly sets forth the steps and reagents to be used, and therefore the metes and bounds of claims 12-13 are clear.

Claims 2-5, 7, 10-13 and 25 are rejected as lacking proper antecedent basis. Applicants have amended the claims as requested by the Examiner, thus obviating this aspect of the rejections.

For the foregoing reasons, Applicants submit that the claims overcome the rejection under 35 U.S.C. 112, second paragraph. Applicants respectfully request reconsideration and withdrawal of the rejection.

**VI. The Rejection of Claims 1-2, 5, 7, 11-13 and 24-25 under 35 U.S.C. 112 (Enablement)**

Claims 1-2, 5, 7, 11-13 and 24-25 are rejected under 35 U.S.C. 112, first paragraph as allegedly lacking enablement. This rejection is respectfully traversed.

It is well settled that "[t]he first paragraph of section 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance." *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). Moreover, "a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *Id.* (emphasis in original).

Applicants submit that the amended claims are fully enabled by the specification. The amended claims are directed to isolated proteases comprising an amino acid sequence which has at least 90% identity with the amino acid sequence shown as amino acids 1 to 226 of SEQ ID NO: 2. Moreover, each of the claims dependent on claim 1, including claim 5, also require the 90% sequence identity with SEQ ID NO:2 and having protease activity. Such is the construction of a dependent claim. See, e.g., 35 U.S.C. 112, fourth paragraph. The specification as filed teaches the cultivation of fungal strain for enzyme purification and gene cloning, purification of the protease, gene cloning of the protease, characterization of protease according to the invention, analysis of protease stability in detergent, expression of a trypsin from *F. solani* in *A. oryzae*, and model detergent wash performance test. See, e.g., Examples I-VII.

Thus, the specification discloses and fully enables the proteases according to the present invention. While some experimentation might be necessary to identify other non-exemplified variants, such experimentation "would not be undue and certainly would not 'require ingenuity beyond that expected of one ordinary skill in the art.'" *In re Angstadt*, 190 USPQ 214, 218 (CCPA 1976).

The Examiner further alleges that claim lacks enablement because Applicants have deposited organisms but there is no indication in the specification as to public availability.

Applicants respectfully submit that the specification as filed states that the biological material was deposited under the terms of the Budapest Treaty. See, e.g., p. 45, lines 27-35. Moreover, Applicants submit herewith a Statement Under 37 C.F.R. 1.808 as requested by the Examiner, thus obviating the rejection.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112, first paragraph. Applicants respectfully request reconsideration and withdrawal of the rejection.

**VII. The Rejection of Claims 1-2, 7, 11-13 and 24-25 under 35 U.S.C. 112 (Written Description)**

Claims 1-2, 7, 11-13 and 24-25 stand rejected under 35 U.S.C. 112, first paragraph as allegedly lacking written description. This rejection is respectfully traversed.

The written description requirement of 35 U.S.C. 112 is satisfied when the specification describes the claimed invention in sufficient detail such that one skilled in the art can reasonably conclude that the inventor(s) was in possession of the claimed invention. See *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). The written description as filed is presumed to be adequate, unless or until sufficient evidence of reasoning to the contrary has been presented by the Examiner to rebut the presumption. See *In re Marzocchi*, 169 USPQ 367 (CCPA 1971).

The amended claims are directed to isolated proteases comprising an amino acid sequence which has at least 90% identity with the amino acid sequence shown as amino acids 1 to 226 of SEQ ID NO: 2 and having protease activity. The specification provides an actual reduction to practice of a protein comprising SEQ ID NO: 2 and describes the complete structure of SEQ ID NO: 2. See, e.g., Sequence Listing for SEQ ID NO: 2. The specification also describes the function of the claimed protease; i.e., protease activity. See, e.g., Examples II and IV. Moreover, all of the claimed proteases share a high degree of structural similarity to SEQ ID NO: 2 (i.e., at least 90% of SEQ ID NO: 2). In view of Applicants' disclosure, those skilled in the art could readily envision all of the amino acid sequences that are 90% identical to SEQ ID NO: 2, for example by comparing a given sequence to SEQ ID NO: 2. The presence of an amino acid sequences that is at least 90% identical to SEQ ID NO: 2 is a structural feature of each of the proteins within the claimed genus. The level of skill in the art is such that one of ordinary skill would be able to make routinely and identify proteases having 90% identity to SEQ ID NO: 2.

Thus, those skilled in the art would have recognized Applicants' specification as filed as showing that Applicants were in possession of the claimed genus at the time of filing.

Therefore, Applicants respectfully submit that the specification contains a sufficient description of the structural and functional characteristics of the claimed proteases to fulfill the requirements of U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **VIII. The Rejection of Claims 1-5, 7, 10-13 and 24-25 under 35 U.S.C. 102 and 103**

Claims 1-5, 7, 10-13 and 24 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Isono et al., 1972, U.S. Patent No. 3,655,570 (hereinafter "Isono") as evidenced by Isono and Esaki et al., 1994, *Arch. Microbiol.* 161(2), 110-115. Claims 1, 5 and 10-13 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Hastrup et al., U.S. Patent No. 5,702,934 (hereinafter "Hastrup") as evidenced by Christakopoulos et al., 1996, *J. Biotechnology* 51(2), 181-189.

Claims 24-25 stand rejected under 35 U.S.C. 103 as allegedly being unpatentable over Isono or Hastrup in view of Okuda et al., US 2004/0002432. The anticipation and obviousness rejections are respectfully traversed.

The cited references disclose proteases. However, none of these references disclose or suggest the proteases recited in the claims as amended herein. Applicants therefore submit that the rejections under 35 U.S.C. 102 and 103 have been overcome, and request reconsideration and withdrawal thereof.

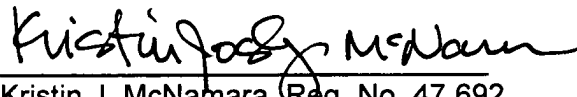
**IX. Conclusion**

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Should any additional fees be due, please charge deposit account no. 50-1701 of Novozymes North America Inc.

Respectfully submitted,

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